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TITLE:
Auricular Therapy for Treatment of Musculoskeletal Pain in the Setting of Military Personnel: A Randomized Trial

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14. ABSTRACT
The research project recently received a NCE to October 29, 2015 due to several delays including transition of the protocol from in theater to the Naval Medical Center San Diego and change of PIs due to deployment. At this point the protocol has obtaining a letter of support from the command at the Naval Medical Center and been approved by the Balboa Navy and UCSD IRBs. We are currently awaiting TATRC final review before initiation of the study.

15. SUBJET TERMS
Auricular Therapy; Musculoskeletal Pain

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Table of Contents

INTRODUCTION:

Musculoskeletal injuries resulting in pain are one of the most common reasons for disability and missed duty among military personnel. Preliminary research has show auricular therapy as a potential adjunctive treatment in this setting. This study will be a randomized trial of 150 subjects examining whether the addition of a specific auricular therapy protocol to standard care will have a beneficial impact on the pain and functionality of subjects who sustain an acute or sub-acute musculoskeletal injury. Specifically, the research study will attempt to determine whether auricular therapy provides a) more rapid and significant pain relief than usual care; b) more rapid and significant relief of co-morbidities related to pain (sleep disruption, mood changes, etc) than usual care; c) more rapid and significant return of functional ability than usual care; and d) more rapid and significant reduction in need for other therapies including pain medication?

BODY:

This research project was initially planned for in theater, but due to difficulty finalizing a clinical site in theater with investigators trained in the protocol (auricular therapy), was moved to the Naval Medical Center San Diego. Subsequently, the initial Balboa Navy PI and several investigators had to be replaced due to deployment. At this point, an updated group of investigators, safety officers and research support staff have been identified and completed initial orientation at the Naval Medical Center San Diego. The protocol has obtaining a letter of support from the command at the Naval Medical Center, approval from the Balboa Navy and UCSD IRBs and granted a no cost extension until October 31, 2015. At this point the protocol is awaiting TATRC final review before initiation.

KEY RESEARCH ACCOMPLISHMENTS:

- Site approval at Naval Medical Center San Diego
- Letter of support obtained from the Naval Command
- Protocol Approval by Navy IRB
- Protocol Approval by UCSD IRB
- Identification of key personal: Navy investigators, safety officer and statistician
- Study questionnaires completed (timeline as attached in Appendix)

REPORTABLE OUTCOMES:

- No reportable outcomes have resulted from this research as of this time.

CONCLUSION:

We are awaiting final TATRC approval and hope for formal study initiation by mid-year 2014.

REFERENCES:

Hauret KG, Jones BH, Bullock SH, Canham-Chervak M, Canada S. Musculoskeletal injuries description of an under-recognized injury problem among military personnel. Am J Prev Med. 2010 Jan;38(1 Suppl):S61-70.

Jennings BM, Yoder LH, Heiner SL, Loan LA, Bingham MO. Soldiers with musculoskeletal injuries. J Nurs Scholarsh. 2008;40(3):268-74.

Goertz CM, Niemtzow R, Burns SM, Fritts MJ, Crawford CC, Jonas WB. Auricular acupuncture in the treatment of acute pain syndromes: A pilot study. Mil Med. 2006 Oct;171(10):1010-4.

APPENDICES / SUPPORTING DATA:

Study timeline

Auricular Therapy Trial: Therapy and Forms Timeline (Tx=Treatment)

	Baseline	Post Tx 1	Weekly	Each Tx*	4 wk Post-Tx
(Overall Forms)					
Consent	X				
Demographics	X				
Pain / Medical History	X				
Current medications, treatments & efficacy	X				
Brief Pain Inventory	X	X	X		X
Pain: 1,2 & 24 hours post-tx		X			
SF-8	X		X		X
Functional Ability Scale	X	X	X		X
Level of Relief		X	X		X
Change in Medication			X		X
(Breakdown by Form)					
Consent	X				
Post Treatment one Form		X			
Brief Pain Inventory		X			
Pain: 1,2 & 24 hours post-tx		X			
Functional Ability Scale		X			
Level of Relief		X			
SF-8					
Weekly Treatment Form			X		
Brief Pain Inventory			X		
Functional Ability Scale			X		
Level of Relief			X		
Change in Medication			X		
SF-8			X		
Post Treatment Form					X
Brief Pain Inventory					X
Functional Ability Scale					X
Level of Relief					X
Change in Medication					X
SF-8					X
Tolerability/Satisfaction					**X**
Clinician Intake Form		X	X	X	X
Pre/Post tx pain level		X	X	X	X
Functional ability		X	X	X	X
Clinician Global Assessment		X	X	X	X
Auricular therapy form**		X	X	X	X

*Use of Clinician Intake form will be based on the frequency of other treatments (i.e. physical therapy)
**For subjects randomized to auricular therapy